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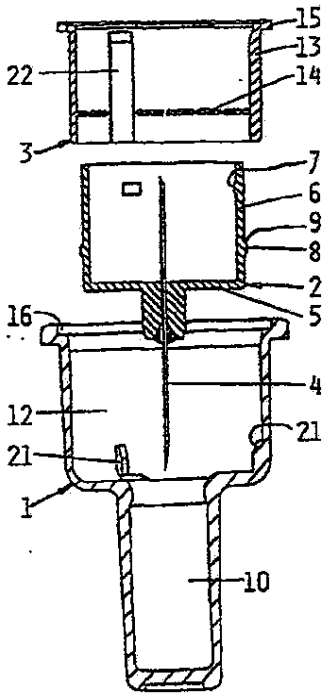
(54) Title: NEEDLE MAGAZINE

(57) Abstract

A magazine for storing and final disposal of a snap-on needle unit (2) has a compartment (1) having a bottom, a cylindric side wall, and an access opening, which compartment accomodates the needle unit with a gap between the outer side wall of this needle unit and the inner side wall of the compartment. A circle of tongue shaped protrusions (14) are at one end thereof hinged at the inner surface of the side wall of the compartment and are at their other end free. The length of the protrusions exceeds the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.



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NEEDLE MAGAZINE

The invention relates to a magazine for storing and final disposal of a snap-on needle unit carrying a needle mounted in a hub comprising a sleeve with an open end for insertion of a needle receiving part of a syringe and exhibiting a cylindric outer wall.

A snap-on needle unit is a unit which may be mounted on a syringe by an axial movement of the syringe and the needle unit towards each other. During this movement a needle receiving part of the syringe is passed into a sleeve of a needle hub forming part of the needle unit until protrusions on the inner surface of the sleeve engage recesses in the needle receiving part.

In opposition to needle units which a screwed onto the syringe an axial pressure must be exerted on the needle unit and the syringe to provide the snap engagement between the two parts. Correspondingly a certain axial force must be used to pull the syringe and the needle unit apart again when after use the needle is removed from the syringe for final disposal.

During mounting and dismounting of the needle unit it is important that the outer pointed end of the needle is protected so that neither the user nor an assisting person scratch himself by this pointed end. Therefore the needle unit is stored in a magazine which covers the needle unit only leaving free the opening wherein the needle receiving part of the syringe shall be inserted.

It is the object of the invention to provide a magazine which may further be used for removing a used needle from the syringe and for keeping it locked in the magazine in a position so that the used needle may not be removed from the magazine after the reinsertion therein. Further it is the object of the invention to show appropriate modifications of the needle unit design which ensures a good collaboration between the needle unit and the magazine.

A magazine according to the invention is characterized in that it has a compartment having a bottom, a cylindric side wall, and an access opening, which compartment accommodates the needle unit with a gap between the outer side wall

of this needle unit and the inner side wall of the compartment, and that a circle of tongue shaped flexible protrusions at one end thereof are hinged at the inner surface of the side wall of the compartment and at their other end are free, the length of the protrusions exceeding the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.

When the needle unit is stored in the magazine the bottom of this magazine supports the needle hub when a needle receiving end of a syringe is pressed into the needle hub to mount this hub onto the syringe. When the needle hub is snap engaged to the syringe it may easily be drawn out of the magazine with the protrusions sliding along the cylindric outer surface of the needle hub. When a used needle unit is reinserted into the magazine the flexible protrusions will have assumed a position wherein the opening defined by the free end of the protrusion has a smaller diameter than has the cylindric part of the needle hub. When the hub is inserted the protrusions will be deflected with their free ends pointing toward the bottom of the compartment until these protrusions assume an oblique position where the cylindric part of the needle unit may pass the free ends of the protrusions which may now slide over the surface of the cylindric part during the further insertion of the needle unit into the magazine. When hereafter the syringe is retracted the protrusions will jam in the gap and retain the needle unit back in the magazine so that pulling the syringe and the magazine away from each other will result in a release of the snap engagement between the needle unit and the syringe.

Not to rely only on the jamming of the protrusions in the gap between the compartment wall and the needle unit the free end of the protrusion abutting the cylindric part of the needle unit may be sharpened so that they will cut into this cylindric part when an attempt is made to move this unit in a direction opposite the direction indicated by the protrusions.

The circle of sharp ended flexible protrusions may appropriately be provided as radially inward extending tongues in a metal ring fixed to the inner wall of the compartment of the magazine.

Due to the locking function of the protrusions the new needle units which are sold stored in the magazine may not just be inserted into the magazine as this would put the protrusion in their locking position. Therefore a special packing technique must be used to ensure that the protrusions of magazines with new needle units ready for use are pointing towards the access opening of the magazine. This may be obtained when the protrusions are provided on the inner surface of sleeve which as a lining is inserted and secured in the compartment. This construction allows that a new and unused needle unit is placed in the magazine whereafter the lining sleeve is inserted in the compartment through the access opening thereof. During the insertion of the lining the free ends of the protrusions will be deflected towards the access opening by the cylindric part of the needle unit already placed in the magazine. With this direction of the protrusions the needle unit may easily be drawn out of the magazine.

The collaboration of the locking means of the magazine and the cylindric part of the needle unit may be enhanced by appropriate design of said cylindric part. This design may consist in the provision of at least one circumferential edge on the cylindric wall of the needle unit. The edge may be drawn past the protrusions as long as these protrusions point away from the edge, but a jamming will occur when the ends of the protrusions abuts against the edge as the protrusion not only have to be deflected but must be crumbled to let the edge pass.

Such an edge may be provided by the ends of a number of circumferentially spaced axial ribs on the cylindric outer wall of the needle unit.

In another embodiment the cylindric part of the needle unit may be provided with a circumferential ring shaped protrusion to provide the circumferential edge.

In still another embodiment the circumferential edge may be provided as the edge of a circumferential recess in the cylindric part of the needle hub.

In the following the invention is further described with reference to the drawings, wherein

Figure 1 shows a sectional view of a not assembled embodiment of a magazine and needle according to the invention,

Figure 2 shows a sectional view of the embodiment in figure 1 assembled for storage,

Figure 3 shows a sectional view of the embodiment in figure 2 with the needle finally disposed of in the magazine,

Figure 4 shows a sectional view of another embodiment of a magazine with a stored needle unit,

Figure 5 shows a locking ring for the magazine shown in figure 4, and

Figure 6 shows an exploded view of an embodiment of a magazine with a needle before assembling.

In figure 1 is shown a magazine 1, a needle unit 2, and a locking sleeve 3 in a position ready to be assembled to store the needle unit in the magazine in a way making it possible to take the needle unit from the magazine and to reinsert the needle unit in the magazine for final disposal.

The needle unit 2 comprises an injection needle 4 carried in a needle hub comprising a bottom 5 which carries a cylindric sleeve 6 surrounding one end of the needle 4 and having at its inner surface protrusions 7 for engagement with recesses in a needle receiving part of a syringe. On its outer surface the sleeve 6 has a circumferential rib 8 exhibiting an edge 9 facing the open syringe receiving end of the sleeve.

The magazine 1 comprises a needle accommodating compartment 10, needle hub support ribs 21, and a sleeve accommodating compartment 12. The needle unit 2 is inserted in the magazine 1 with the end of the needle not surrounded by the sleeve 6 inserted in the compartment 10 and the bottom 5 of the needle hub abutting against the needle support ribs 21. Thereby the sleeve 6 will be centered in the compartment 12 leaving a uniform gap between the outer surface of the sleeve 6 and the inner surface of the cylindric wall of the compartment 12 allowing the locking sleeve 3 to be pressed in through an open end of the compartment 12.

The locking sleeve 3 has a cylindric wall 13 which is at its inner surface along a circle in a plane perpendicular to the axis of the sleeve 13 provided with tongue shaped projections 14 which are flexible in their connection to the inner wall of the locking sleeve 13 and which extend radially so that the circle defined by their free ends has a minor diameter than has the needle hub. Consequently, when the locking sleeve 3 is inserted in the gap between the needle hub and the inner wall of the compartment 12 the needle hub will abut the projections 14 and deflect them to adopt an oblique position with their free ends pointing towards the open end of the magazine as shown in figure 2. The locking sleeve 3 is secured in the compartment 12, e.g. by having a flange 15 which is received in a recess 16 surrounding the access opening of the magazine and a gluing or welding being established between the flange 15 and the recess 16. Alternatively an irreversible snap lock connection may be provided between the outer surface of the locking sleeve and the inner cylindric surface of the compartment 12.

When the needle unit 2 is positioned in the magazine 1 and the locking sleeve is inserted in the gap between the needle hub and the magazine the magazine is closed by a membrane 17 covering the access opening of the magazine and the needle unit may in this way be maintained sterile as long as it is stored in the magazine. The membrane may be made from paper which does not allow germs to pass but is permeable to hot steam used to sterilize the needle unit in the magazine.

When the needle unit is going to be used, the membrane 17 is removed and the needle receiving part of a syringe is inserted into the open end of the sleeve 6

and moved into this sleeve until the protrusions 7 engages the recesses in the needle receiving part of the syringe. When the syringe is retracted the needle unit will follow this syringe due to the snap connection between this needle unit and the syringe. The protrusion 8 of the needle hub may pass the tongues of the locking sleeve as these tongues are passed in a direction allowing them to be further deflected. When the needle unit is removed from the magazine the tongues will due to their flexibility return to a position with their free ends defining a circle having a diameter smaller than the diameter of the needle hub.

When after use the needle hub mounted on the syringe is reinserted in the magazine the needle hub will abut the tongues and deflect them to an oblique position with their free ends pointing away from the access opening of the magazine. During further insertion of the needle unit the protrusion 8 of this unit may pass the tongues and after this passing the needle unit is locked in the magazine as a retraction will cause the free ends of the tongues to abut against the edge 9 and consequently the force exerted on the tongues during a retraction of the needle unit is not a deflecting one but a force in the longitudinal direction of the tongues so that the tongues must be crumbled before the needle unit may be removed from the magazine. For such a crumbling a force is needed which far exceeds the force needed to release the snap connection between the needle unit and the syringe, and consequently the needle unit will remain in the magazine when the syringe is retracted.

In the shown embodiment the needle unit was designed for use with the magazine by having an edge 9 facing the access opening of the magazine. This edge 9 is provided on a circumferential protrusion 8 of the needle unit. The edge may alternatively be provided as end surfaces of circumferentially spaced ribs on the outer surface of the sleeve 6 or as an edge of a circumferential recess in this outer surface.

In a more universal embodiment of the magazine no special designed needle unit is demanded. In such an embodiment tongues 14 having a sharp free end are provided as radially inward pointing tongues of metal or a hard plastic. The sleeve

13 and the tongues 14 are preferably moulded as one integral part. However, if different materials are used for the sleeve and the tongues, a flat ring 18 is provided with radial inward pointing tongues 14 as shown in figure 5. This ring has a diameter corresponding to the diameter of the access opening of the magazine. When the needle unit is positioned in the magazine the ring is placed in the gap between the needle unit and the wall of the compartment 12 so that the needle hub deflects the tongues 14 to an oblique position with their free ends abutting the outer surface of the sleeve 6. The ring 18 is placed so it abuts a shoulder formed by ends of the needle hub supporting ribs 21 and is secured in this position by a sleeve 20 inserted from the access opening of the magazine as shown i figure 4. During the first removal and the reinsertion of the needle hub the tongues 14 will function in the same way as the tongues 14 in figure 1 - 3, but if an attempt is made to remove the reinserted needle unit from the magazine the sharp free end of the tongues will cut into the surface of the needle hub and provide a detent against removal of the needle unit. This function is not depending on the needle unit design and the protrusions 8 shown in figure 4 are not actually needed.

Figure 6 shows an exploded view of a magazine with a needle unit. In this figure it is seen that some of the tongues in the locking sleeve are replaced by axial guiding ribs 22 which abutting an outer circumferential surface of the needle unit contribute to the centering of the needle unit in the magazine.

Claims

1. A magazine for storing and final disposal of a snap-on needle unit carrying a needle mounted in a hub comprising a sleeve with an open end for insertion of a needle receiving part of a syringe and exhibiting a mainly cylindric outer wall, characterized in that the magazine has a compartment having a bottom, a cylindric side wall, and an access opening, which compartment accommodates the needle unit with a gap between the outer side wall of this needle unit and the inner side wall of the compartment, and that a circle of tongue shaped protrusions at one end thereof are hinged at the inner surface of the side wall of the compartment and at their other end are free, the length of the protrusions exceeding the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.

2. A magazine according to claim 1, characterized in that the free end of the protrusions abutting the cylindric part of the needle unit are sharpened.

3. A magazine according to claim 2, characterized in that the protrusions are provided as radially inward extending tongues in a metal ring fixed at the inner wall of the compartment of the magazine.

4. A magazine according to anyone of the claims 1 - 3, characterized in that the protrusions are provided on the inner surface of a sleeve which as a lining is inserted and secured in the compartment.

5. A needle hub for use in a magazine according to the claims 1-4, characterized in that on the mainly cylindric outer wall of the needle unit at least one circumferential edge is provided facing the open end of the sleeve.

6. A needle hub according to claim 5, characterized in that the edge is defined by the ends of a number of circumferential spaced axial ribs on the cylindric outer wall of the needle unit.

7. A needle hub according to claim 5, characterized in that the edge is provided by the cylindric outer wall of the needle unit being provided with a circumferential ring shaped protrusion.

8. A needle hub according to claim 5, characterized in that the edge is provided as an edge of a circumferential recess in the cylindric outer wall of the needle hub.

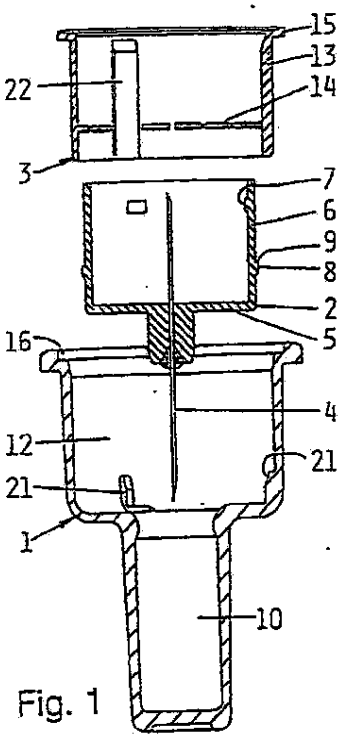

Fig. 1

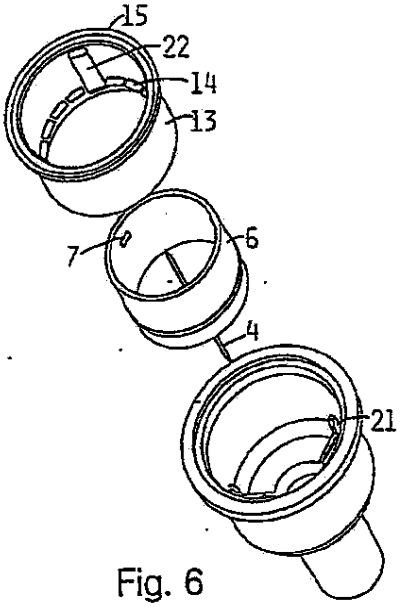

Fig. 6

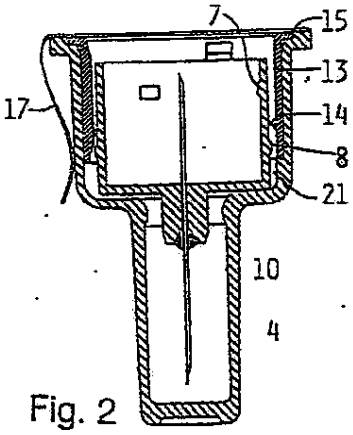

Fig. 2

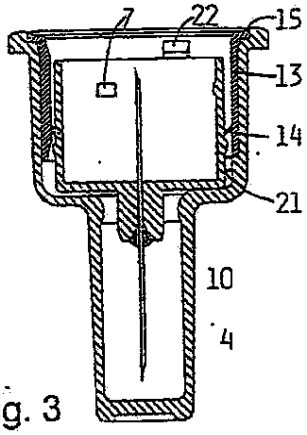

Fig. 3

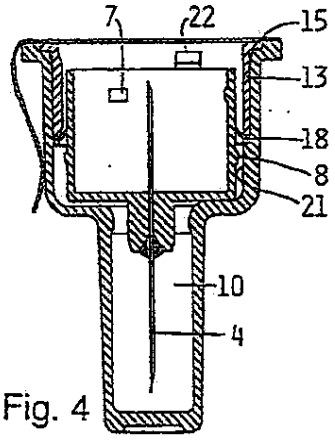

Fig. 4

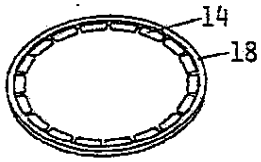

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 95/00306

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/32
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 8200412 A1 (ELISHA, BENJAMIN), 18 February 1982 (18.02.82), page 4, line 18 - line 27, figure 2	1-4
X	figure 3	5,7

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search	Date of mailing of the international search report
10 October 1995	10-11-1995
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer May Hallne Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT
Information on patent family members

28/08/95

International application No.
PCT/DK 95/00306

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A1- 8200412	18/02/82	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

GP 3734

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3734

Filed: July 7, 1999 Examiner: To be assigned

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

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PATENT

#

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3734

Filed: July 7, 1999 Examiner: To be assigned

For: Medication Delivery Device

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Carol McFarlane
(name of person mailing paper)

Carol McFarlane
(signature of person mailing paper)

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3734

Filed: July 7, 1999 Examiner: TBA

For: Medication Delivery Device

REQUEST FOR CORRECTED FILING RECEIPT

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Washington, DC 20231

Sir:

Applicants filed the above-captioned application on July 7, 1999.

The filing receipt received by Applicants incorrectly indicates the city of residence for inventor Munk as Hvidorre. The correct city of residence is Vanlose. A copy of the filing receipt is attached to this request.

Applicants therefore request the issuance of a corrected filing receipt with the correct city of residence.

Applicants submit that the error was the fault of the USPTO. Therefore, a fee for this service is not required.

Respectfully submitted,

Date: January 21, 2000

Carol E. Rozek

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C

PTO-103X (Rev. 6-99)

FILING RECEIPT

CORRECTED

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Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/348,536	07/07/99	3734	$980.00	5637.200-US	2	25	2

STEVE T ZELSON ESQ
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OIPE JC62 JAN 31 2000 PATENT & TRADEMARK OFFICE

NOV 29 1999

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts of Application" ("Missing Parts Notice") in this application, please submit any corrections to this Filing Receipt with your reply to the "Missing Parts Notice." When the PTO processes the reply to the "Missing Parts Notice," the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s) THOMAS BUCH-RASMUSSEN, GENTOFTE, DENMARK; BENNY MUNK, HVIDORRE, DENMARK; JENS ULRIK POULSEN, VIRUM, DENMARK; HENRIK LJUNGREEN, BALLERUP, DENMARK; PETER MOLLER JENSEN, HORSHOLM, DENMARK; JENS MOLLER JENSEN, COPENHAGEN K, DENMARK.

CONTINUING DATA AS CLAIMED BY APPLICANT-
PROVISIONAL APPLICATION NO. 60/098,702 09/01/98

FOREIGN APPLICATIONS- DENMARK PA 1998 00909 07/08/98
DENMARK PA 1998 01500 11/17/98

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 08/03/99
TITLE
MEDICATION DELIVERY DEVICE

PRELIMINARY CLASS: 604

DATA ENTRY BY: PERRY, REGINA TEAM: 02 DATE: 11/18/99

(See reverse for new important information)

GAU 3763

Docket No. 5637.200-US

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Date: October 25, 2000

Applicant(s)	:	Buch-Rasmussen et al.	
Serial No.	:	09/348,536	Examiner: Simons, K.
Filed	:	July 7, 1999	Art Unit: 3763
Title	:	Medication Delivery Device	

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

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Robert B. Smith — Reg. No. 28,538

Robert B. Smith — October 25, 2000
Signature — Date

Transmitted herewith is an Amendment in application.

1. ( ) No additional fee is required.

GAU 3763

Docket No. 5637.200-US

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Date: October 25, 2000

Applicant(s)	:	Buch-Rasmussen et al.	
Serial No.	:	09/348,536	Examiner: Simons, K.
Filed	:	July 7, 1999	Art Unit: 3763
Title	:	Medication Delivery Device	

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2000

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — October 25, 2000
Signature — Date

Transmitted herewith is an Amendment in the above-identified application.

1. ( ) No additional fee is required.

Docket No. 5637.200-US

2. ( ) The fee has been calculated as shown below:

Claims remaining	Prior Paid Claims	Extra		Rate	Fee
Total:	minus (at least 20) =		@	$18	= $
Independent	minus (at least 3) =		@	$80	= $

TOTAL ADDITIONAL FEE: $

3. (X) An extension of time to respond to the PTO Communication dated April 26, 2000 is hereby requested. The required fee is indicated below:

Within first month:	( )	$110
Within second month	( )	$390
Within third month	(X)	$890
Within fourth month	( )	$1,390

4. ( ) The Amendment includes an Information Disclosure Statement. Enclosed is Form PTO-1449 and copies of ____ reference(s).

5. (X) The Commissioner is hereby authorized to charge the amount of $ 890.00 representing (a) additional claims fee ($); (b) the extension fee ($ 890); and (c) the fee for filing an Information Disclosure Statement ($) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 735-3020

Docket No. 5637.200-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/348,536 Examiner: Simons, K.

Filed : July 7, 1999 Art Unit: 3763

Title : Medication Delivery Device

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2000.

Robert B. Smith Reg. No. 28,538

Robert B. Smith October 25, 2000
Signature Date

October 25, 2000

AMENDMENT

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

In response to the Office Action dated April 26, 2000, please amend the application as indicated below.

IN THE SPECIFICATION:

On page 1, line 23, change "displaced" to - - replaced - -;

On page 2, line 7, change "minimised" to - - minimized - -; and

on line 27, change "coupling(s) secure(s)" to - - coupling or couplings ensure - -;

On page 3, line 11, change "as to secure" to - - so as to ensure - -; and

On page 9, line 21, change "effect" to - - cause - -.

IN THE CLAIMS:

Please cancel claim 1 and substitute the following claim therefor:

- - 26. A medication delivery device comprising a cartridge assembly having opposite ends, and a dosing assembly for setting a desired dose and acting on said cartridge assembly to cause such dose to be delivered,

wherein said cartridge assembly includes a molded cartridge and a stopper disposed in said cartridge, wherein one end of said cartridge assembly is sealed with a pierceable sealing, wherein said one end includes a first coupling means for releasably mounting a needle assembly having a skin-piercing needle, and wherein the other end of said cartridge assembly includes a second coupling means for engaging said dosing assembly, wherein at least one of said coupling means is unitarily molded with the cartridge, and

wherein said dosing assembly includes a housing, a plunger, and a mechanism for setting a desired dose and for moving said plunger, relative to said housing, in an axial direction for administering a set dose, and wherein said dosing assembly housing includes a coupling member for engaging said second coupling means of said cartridge assembly for securing said housing against axial movement relative to said cartridge assembly and such that said plunger engages said stopper for moving said stopper in response to plunger movement. - -

Rewrite claims 2-6 as follows:

- - 2. (Twice Amended) The medication delivery device according to claim [1] 26, wherein [all the] both said coupling means of [the] said cartridge assembly are unitarily [moulded] molded with the cartridge.

3. (Twice Amended) The medication delivery device according to claim [1] 26, wherein the said at least one coupling means of [the] said cartridge assembly is an external coupling.

4. (Twice Amended) The medication delivery device according to claim [1] 26, wherein the said at least one coupling means of [the] said cartridge assembly is a threaded coupling.

5. (Twice Amended) The medication delivery device according to claim 4, wherein [the] said second coupling means [for engaging to dosing means] is an external threaded coupling.

4.6. (Twice Amended) The medication delivery device according to claim [1] ~~26~~, wherein the cartridge is [moulded] molded of a plastic material. - -

Cancel claims 8-9 and 11 without prejudice.

Rewrite claims 10 and 12 as follows:

- - ~~10~~. (Twice Amended) The medication delivery device according to claim [1] ~~26~~, wherein the [cartridge] dosing assembly further comprises a scale.

12. (Twice Amended) The medication delivery device according to claim [1] ~~26~~, wherein the coupling means of the cartridge assembly are opposed [each to one another. - -

Cancel non-elected claims 13-25 without prejudice.

Add the following claims:

- - 27. The medication delivery device according to claim 26, wherein the said at least one coupling means is said second coupling means.

28. The medication delivery device according to claim 27, wherein said second coupling means is a threaded coupling. - -

C5

REMARKS

By the foregoing amendments, the specification has been amended to make several idiomatic revisions. Also, as discussed further below, claim 1 has been cancelled, and new claim 26 is submitted, to overcome the formal rejection raised to claim 1 and to define, with greater particularity, the novel features of the invention.

The applicants note that the restriction requirement has been made final, and have canceled non-elected claims 13-25 without prejudice to filing a divisional application.

In paragraph 2 of the April 26, 2000 Office Action, the Examiner objects under Rule 83(a) to the drawings because the reinforcements, cartridge housing, and non-circular cartridge cross-sections recited in dependent claims 8, 9, and 11 are not shown in the drawings. Because such features are covered generically in other claims, and to advance the prosecution of the present application, the applicants have merely canceled such claims rather than amend the drawings. Applicants have canceled such claims, however, without prejudice to reintroducing

such claims, with corresponding drawing amendments, at a future time if deemed appropriate.

In paragraphs 3-5 of the Office Action, the Examiner raises certain formal rejections as to the language of claims 1, 8, 9, and 11. As noted above, claims 8-9 and 11 have been canceled. With respect to claim 1, the Examiner rejected such claim under 35 U.S.C. § 112, second paragraph, on the grounds that it was not clear whether the applicants were claiming the needle assembly per se. Claim 1 has been rewritten as new claim 26, where it is clear that, while the claimed device includes a fitting for receiving a needle assembly, the needle assembly per se is not part of the claimed device.

Original claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Reynolds U.S. patent No. 5,364,369. Reynolds discloses, in Figure 6, a medication delivery device adapted for an injection needle. The Reynolds device includes a cartridge (mis-labeled "8" in Figure 6), which Reynolds refers to as a vial, having a stopper 8 (the stopper is not labeled in Figure 6), and a plunger 10 which can push the stopper 8 forward to expel a dose of medicine through the needle 28. The forward end of Reynold's syringe includes a pierceable membrane 5. An outer cap 2, having a needle 22 to pierce the membrane 5, can be mounted on the forward end of the cartridge 6. In turn, a needle assembly, with a skin-piercing needle 28, can be mounted on the outer cap 2.

As shown in other figures, when the Reynold's cartridge 6 holds only one part of a medicament mixture, prior to using the syringe, a capsule 14 containing the other ingredient, i.e., a liquid, and a cap 12, are pressed into the bore of the plunger 10. A needle 44 on the cap 12 allows the liquid in the capsule 14 to enter the bore of the cartridge 6 and mix with the dry medicament. The capsule 14 and cap 12 are then removed, in preparation for using the syringe (see Fig. 5).

New claim 26 recites a medication delivery device comprising a cartridge assembly and a dosing assembly for setting and administering a desired dose. The cartridge assembly includes a molded cartridge. Opposite ends of the cartridge assembly include first and second coupling means for engaging a needle assembly having a skin-piercing needle and the dosing assembly, respectively. At least one of the coupling means is molded unitarily with the cartridge.

Claim 26 further recites that the dosing assembly includes a housing, a plunger, and a mechanism for setting a desired dose and for moving the plunger, relative to the housing, in an axial direction for administering a set dose. Also, the housing includes a coupling member, e.g., threads, for engaging the second coupling means of the cartridge assembly so as to secure the housing against axial movement relative to the cartridge assembly and such that the plunger engages the stopper. In such manner, when the dosing assembly moves the plunger, the plunger moves the stopper forward to eject the set dose.

As noted above, claim 26 recites that at least one of the two coupling means on the cartridge assembly is molded integrally with the cartridge itself. Reynolds discloses a means at its forward end for mounting a needle assembly with a skin-piercing needle 28, but such means is the cap 2. The cap 2 and cartridge 6 are separate parts, and thus Reynolds does not have the recited integrally molded coupling means at its forward end.

Reynolds also lacks any dosing assembly as now defined in claim 26. In particular, Reynolds does not have any mechanism to set a dose and to move a plunger to administer the set dose. Nor does Reynolds have a housing associated with its plunger or any coupling means which can secure the cartridge 6 and such a housing against relative axial movement.

For such reasons, the applicants respectfully submit that Reynolds neither anticipates nor suggests the invention as recited in claim 26, and favorable consideration and allowance of new claim 26 are respectfully requested.

Claim 2 recites that both the recited couplings on cartridge assembly are molded integrally with the cartridge. As noted above, the needle coupling of the Reynolds cartridge is not molded integrally with its cartridge 6, and Reynolds lacks any coupling for a dosing assembly. Thus, allowance of claim 2 is respectfully requested for such additional reason.

New claim 27 recites that the said at least one coupling (i.e., the coupling which is molded integrally with the cartridge) is the second coupling, i.e., the coupling for engaging the dosing assembly housing. Claim 28 recites that this second coupling is a threaded coupling. As noted above, Reynolds has no coupling, as recited in claim 26, between the capsule 14 and the cartridge. For such reason, as well as other reasons recited in connection with claim 26, favorable consideration and allowance of claims 27-28 are respectfully requested.

With respect to the remaining dependent claims, favorable consideration and allowance of such claims are respectfully requested for the reasons recited in connection with claim 26.

In light of the foregoing amendments and remarks, favorable reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/348,536	07/07/99	BUCH-RASMUSSEN	T 5637.200-US

QM12/0117

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EXAMINER	
SIRMONS,K	
ART UNIT	**PAPER NUMBER**
3763	#13

DATE MAILED: 01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95) U.S. G.P.O. 1999-459-833 1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/348,536	Thomas Bush-Rasmussen et al
Examiner	**Group Art Unit**
Kevin C. Simmons	3763

☒ Responsive to communication(s) filed on Oct 27, 2000

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 2-7, 10, 12, and 26-28 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2-7, 10, 12, and 26-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. Claims 26-28, 2-5, 7 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Reynolds U.S. Pat. No. 6,146,361.

DiBiasi et al discloses a medication delivery device comprising: a cartridge assembly (22) having opposite ends, and a dosing assembly (38), wherein said cartridge assembly includes a molded cartridge (22) and a stopper disposed in said cartridge (36), wherein one end of said cartridge assembly is sealed with a pierceable sealing (32), wherein said one end includes a first coupling means for releasably mounting a needle assembly having a skin-piercing needle (88), and wherein the other end of said cartridge assembly includes a second coupling means for engaging said dosing assembly (13), wherein at least one of said coupling means is unitarily molded with the cartridge (13, 88), and wherein said dosing assembly includes a housing (38), plunger (distal end of 44), and a mechanism for setting a desired dose and for moving said plunger (col. 3, lines 20-23),

relative to said housing in an axial direction for administering a set dose (functional language), (fig. 1), and wherein said dosing assembly housing includes a coupling member (41) for engaging said second coupling means of said cartridge assembly (fig. 1); for securing said housing against axial movement relative to said cartridge assembly and such that said plunger engages said stopper for moving said stopper in response to plunger movement (fig.1); wherein both said coupling means of said cartridge assembly are unitarily molded with the cartridge (figs. 1 and 2); wherein the said at least one coupling means of said cartridge assembly is an external coupling (13, 88); wherein the said at least one coupling means of said cartridge assembly is a threaded coupling (13, 88); wherein said second coupling means is an external threaded coupling (13); wherein the coupling of the cartridge assembly are opposed (figs. 1 and 2); wherein the said at least one coupling means is said second coupling means (figs. 1 and 2); wherein said second coupling means is a threaded coupling (figs. 1 and 2); wherein the cartridge is at least partly transparent (figs. 1 and 2).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiBiasi et al U.S. Pat. No. 6,146,361 in view of Sams U.S. Pat. No. 4,865,591.

DiBiasi discloses a medication delivery device substantially as claimed except for: wherein the dosing assembly further comprise a scale and wherein the cartridge is molded of a plastic material. However, Sams discloses a dosing assembly with a scale.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cartridge of DiBiasi using the scale as taught by Sams, since Sams discloses that the scale will indicate to the user the amount of dosage selected for injection. Furthermore, it would have been an obvious matter of design choice to mold the cartridge from a plastic material, since applicant has not disclosed that a molded plastic cartridge solves any stated problem or is form any particular purpose and it appears that the invention would perform equally well with glass.

Response to Arguments

5. Applicant's arguments with respect to claims 2-7, 10, 12, and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703)306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS

Kevin C. Sirmons

Patent Examiner

1/09/01

RICHARD K. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

ATTACHMENT TO AND MODIFICATION OF NOTICE OF ALLOWABILITY (PTO-37)

(November, 2000)

NO EXTENSIONS OF TIME ARE PERMITTED TO FILE CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION, notwithstanding any indication to the contrary in the attached Notice of Allowability (PTO-37).

If the following language appears on the attached Notice of Allowability, the portion lined through below is of no force and effect and is to be ignored[1]:

~~A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).~~

Similar language appearing in any attachments to the Notice of Allowability, such as in an Examiner's Amendment/Comment or in a Notice of Draftperson's Patent Drawing Review, PTO-948, is also to be ignored.

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[1] The language which is crossed out is contrary to amended 37 CFR 1.85(c) and 1.136. See "*Changes to Implement the Patent Business Goals*", 65 *Fed. Reg.* 54603, 54629, 54641, 54670, 54674 (September 8, 2000), 1238 *Off. Gaz. Pat. Office* 77, 99, 110, 135, 139 (September 19, 2000).

FORM PTO-892 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NO.	
NOTICE OF REFERENCES CITED	09348536	3763		13
	APPLICANT(S) Buch-Rasmussen et al			

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	A	6,146,361	11/2000	DiBiasi et al.	604	232	
	B						
	C						
	D						
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS
	L						
	M						
	N						
	O						
	P						
	Q						

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	R	
	S	
	T	
	U	

EXAMINER	DATE	
Kevin C. Simmons	January 10, 2001	Form892ccs2103b

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05(a).)

US006146361A

United States Patent [19]

DiBiasi et al.

[11] Patent Number: 6,146,361

[45] Date of Patent: *Nov. 14, 2000

[54] MEDICATION DELIVERY PEN HAVING A 31 GAUGE NEEDLE

[75] Inventors: Michael D. DiBiasi, West Milford; Elizabeth A. Harbin, Wayne; Robert E. West, Morristown, all of N.J.

[73] Assignee: Becton Dickinson and Company, Franklin Lakes, N.J.

[*] Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

[21] Appl. No.: 08/721,368

[22] Filed: Sep. 26, 1996

[51] Int. Cl.[7] A61M 5/00

[52] U.S. Cl. 604/232; 604/272

[58] Field of Search 604/232, 233, 604/234, 272, 207, 208, 211, 187

[56] References Cited

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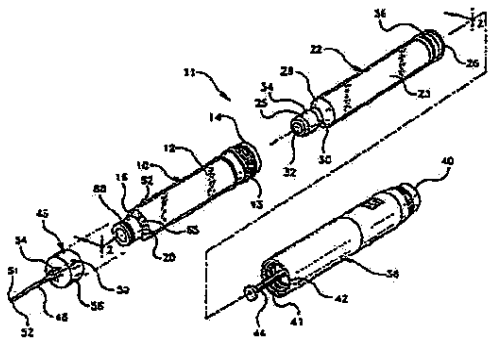
(List continued on next page.)

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Alan W. Fiedler

[57] ABSTRACT

A needle assembly for a medication delivery pen having a 31 gauge needle cannula that reduces penetration force during an injection process resulting in less pain to the patient without causing any loss in performance or structural integrity.

9 Claims, 2 Drawing Sheets



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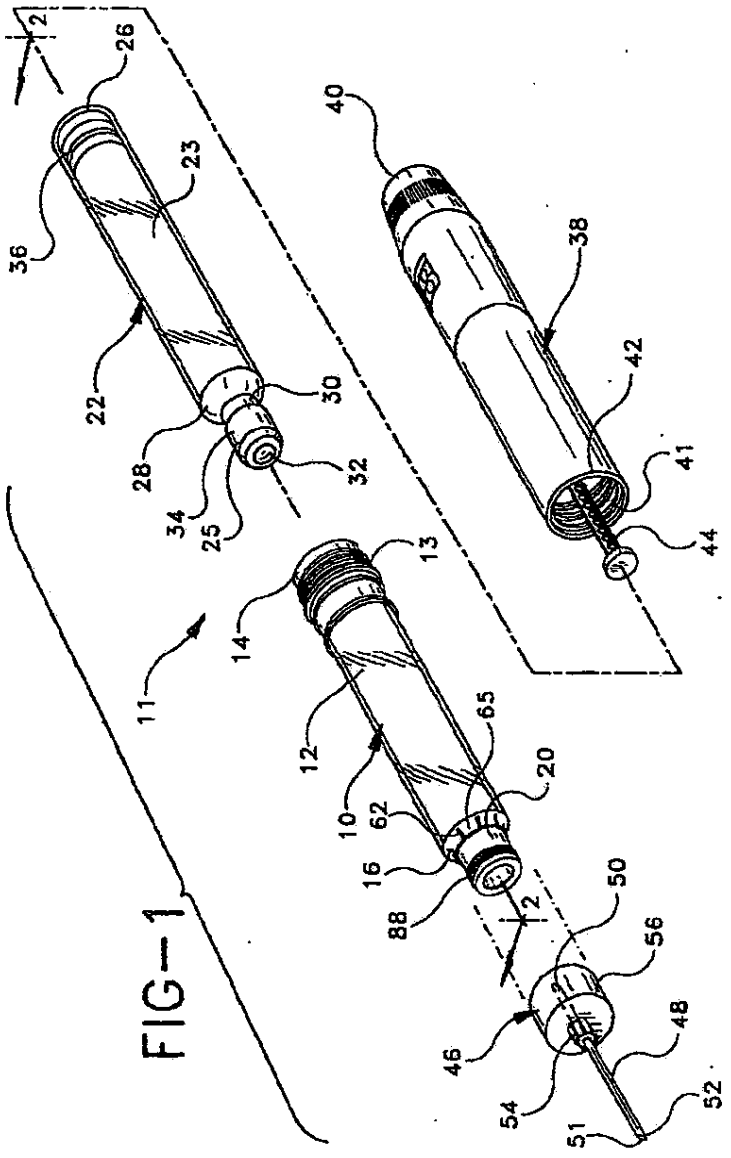
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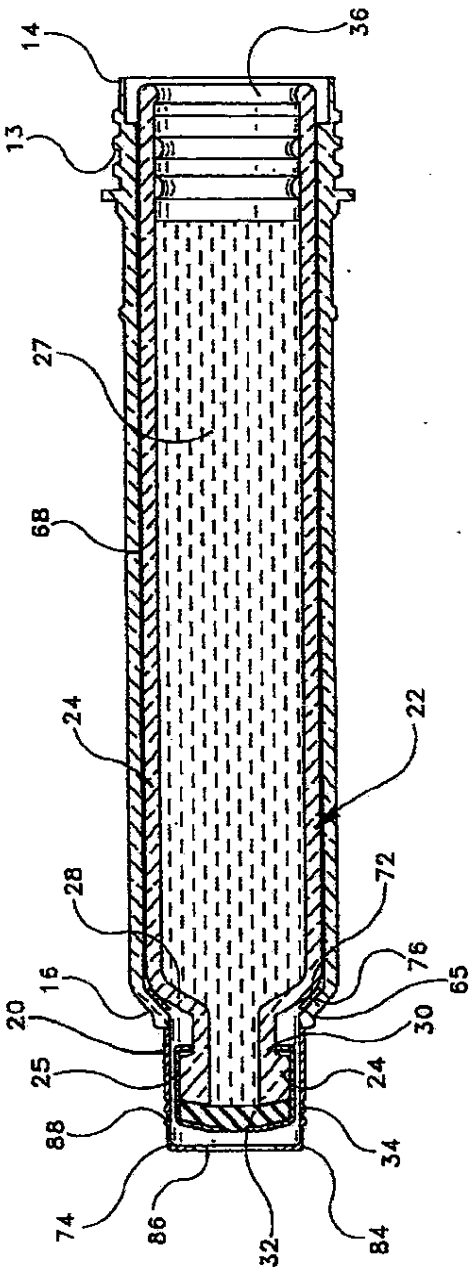
FIG-1



FIG—2

MEDICATION DELIVERY PEN HAVING A 31 GAUGE NEEDLE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The subject invention relates to a medication delivery pen having a 31 gauge needle.

2. Background Description

Medication delivery pens are hypodermic syringes used for self-injection of precisely measured doses of medication. Pens are widely used, for example, by diabetics to dispense insulin.

A typical prior art medication delivery pen includes a cartridge which contains a volume of liquid medication sufficient for several doses. The cartridge includes an elongated generally tubular glass cartridge having a pierceable rubber septum which extends across the open distal end of the cartridge and is securely held in position by a metallic sleeve that is crimped to the distal end of the cartridge. The cartridge also includes a rubber stopper in sliding fluid-tight engagement with interior walls of the cartridge.

Such a medication delivery pen also includes a unitarily molded cartridge retainer having a small diameter tubular neck dimensioned for tightly engaging the neck of the cartridge and the metallic sleeve crimped thereon so as to support and position the entire cartridge. Exterior regions at the extreme distal end of the tubular neck are formed with an array of threads for threadedly receiving the mounting cap of a needle assembly. The medication delivery pen further includes a dosing apparatus that is engaged with the proximal end of the cartridge retainer having a plunger for engaging the rubber stopper of the cartridge. The dosing apparatus includes a dose setting structure used to select the longitudinal distance through which the plunger will move, and dispensing means for driving the plunger the selected distance.

The needle assembly for the medication delivery pen includes an elongate needle cannula having opposed proximal and distal points and a lumen extending therethrough. A plastic cork is adhered to an intermediate position along the needle cannula and in turn is rigidly connected to an end wall of a cylindrical cap. The cylindrical wall of the cap surrounds the proximal point on the needle cannula and includes an array of internal threads for engaging the external threads on the neck of the cartridge retainer.

The medication delivery pen may be used by urging the cap of the needle assembly over the neck of the cartridge retainer sufficiently for the proximal point of the needle cannula to pierce the rubber septum of the cartridge. The cap is then rotated to threadedly engage the neck of the cartridge retainer. The user then manipulates the dosing apparatus to select an appropriate dose. A protective shield over the distal end of the needle cannula is then removed, and the distal point of the needle cannula is injected. The user then actuates the dispensing means of the prior art dosing apparatus to urge the stopper of the cartridge distally and to deliver medication through the lumen of the needle cannula. The needle is then withdrawn, and the needle assembly is separated from the cartridge retainer and safely discarded. The rubber septum of the cartridge reseals itself, and may be pierced again for a subsequent administration of medication. This process may be carried out repeatedly until all of the medication in the cartridge has been used.

A problem with currently available needle assemblies for use on medication delivery pens is the size of the cannula.

Prior to the present invention, 27, 28, 29 and 30 gauge needle cannulas have been commonly used on medication delivery pens, with 30 gauge being the smallest diameter possible. Even though smaller gauges, i.e., 29 and 30 gauge, have helped to reduce pain to patients during injection, there is still a need to provide needle assemblies for medication delivery pens with smaller cannula diameters since small diameter needles are perceived by patients to cause less pain during the injection. However, no one skilled in the art has suggested and no one has provided patients with needle assemblies having a diameter less than 30 gauge.

SUMMARY OF THE INVENTION

The present invention overcomes the 30 gauge limit that has existed for pen needle assemblies by providing a 31 gauge needle assembly for use on medication delivery pens. The 31 gauge needle provides a patient with a needle assembly having a smaller cannula size without loss in performance or structural integrity. The 31 gauge needle assembly mounts on a needle mounting tip of a cartridge retainer assembly on a medication delivery pen and is used like prior art needle assemblies to pierce a patient's arm during an injection process.

However, since the 31 gauge needle cannula is smaller than prior art needle cannulas the penetration force is decreased which reduces the pain caused during an injection procedure. In addition, the smaller cannula size will be seen by the patient prior to the injection so that perceived pain or anticipated pain is also reduced. The reduction in actual and perceived/anticipated pain provided by using the 31 gauge needle on the medication delivery pen is a major benefit to patients that need numerous injections each day, i.e., diabetics requiring insulin injections.

These and other aspects, features and advantages of the present invention will become apparent from the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view of a medication delivery pen having a needle assembly in accordance with the subject invention; and

FIG. 2 is a cross-sectional view of a cartridge retainer assembly of the medication delivery pen.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

A needle assembly for use on a medication delivery pen 11, in accordance with the subject invention, is identified generally by the numeral 46 in FIG. 1. As shown in FIG. 1 medication delivery pen 11 includes a cartridge retainer assembly 10, a dosing apparatus 38 and a cartridge assembly 22. Needle assembly 46, as described in more detail below, is designed to be attached to a needle mounting insert tip 20 on cartridge retainer assembly 10.

Cartridge retainer assembly 10, as shown in FIGS. 1 and 2, includes an elongate generally tubular body 12 with opposed proximal and distal ends 14 and 16, respectively. A generally tubular needle mounting insert tip 20 is snap-fit mounted in distal end 16 of body 12 and cartridge retainer assembly 10 is dimensioned and configured to receive a cartridge assembly 22 therein.

Cartridge assembly 22 includes an open proximal end 26 and a distal end 25 defined by an inwardly converging shoulder 28. A small diameter neck 30 projects distally from

shoulder 28 on cartridge assembly 22, and is provided with a large diameter annular bead 24 extending circumferentially thereabout at the extreme distal end of neck 30. A pierceable and resealable rubber septum 32 extends completely across the open distal end defined by neck 30. Rubber septum 32 is held in place by a metallic sleeve 34 which is crimped around bead 24 at the distal end of neck 30. Medication such as insulin or heparin is pre-filled into cartridge assembly 22 and is retained therein by a rubber stopper 36. Stopper 36 is in sliding fluid-tight engagement with the tubular wall of cartridge assembly 22. Distally directed forces on stopper 36 urge the medication from pen 11 as explained further below.

Dosing apparatus 38 in medication delivery pen 11 is generally cylindrical and includes opposed proximal and distal ends 40 and 42, respectively. Threads 41 are disposed at distal end 42 of dosing apparatus 38 for releasable threaded engagement with proximal end 14 of body 12 of cartridge retainer assembly 10. A plunger rod 44 projects distally from dosing apparatus 38 and is dimensioned to engage stopper 36 of cartridge assembly 22. Dosing apparatus 38 also includes known mechanisms for setting a selected dose of medication to be delivered by pen 11. A dispensing mechanism (not shown) is operative to drive plunger rod 44 a selected distance in a distal direction for moving stopper 36 a distance that will inject the selected dose of medication from cartridge assembly 22. Although a particular prior art dosing apparatus 38 is depicted in FIG. 1, it is to be understood that other dosing apparatus can be used with the needle assembly of the subject invention.

Needle assembly 46, according to the present invention, includes a 31 gauge needle cannula 48 with opposed proximal and distal tips 50 and 52, respectively, and a lumen 51 extending entirely therethrough. The dimensions of 31 gauge needle cannula 48 are set forth below:

Parameter	Value
Outer Diameter	0.010"-0.0105"
Inner Diameter	0.005"-0.006"
Wall Thickness	0.00225"-0.00275"
Usable length	0.315" (8 mm)
Cannula Material	Stainless Steel

Of course, 31 gauge needle cannulas of other lengths can also be used, i.e., 0.236" (6 mm) or 0.394" (10 mm), and still remain within the scope of the present invention. A cork 54 is securely affixed at an intermediate position along needle cannula 48, and a cap 56 is securely affixed to cork 54. Cap 56 of needle assembly 46 includes an array of internal threads (not shown) for removable mounting needle assembly 46 to needle mounting insert tip 20 on cartridge retainer assembly 10. It is to be understood, however, that other releasable engagement means between needle assembly 46 and cartridge retainer assembly can be provided. For example, external threads can be formed on needle assembly 46 and corresponding internal threads can be defined on cartridge retainer assembly 10 or a bayonet style mounting using lugs and slots can be used. In addition, needle assembly 46 could be "snap fit" on to cartridge retainer assembly 10.

As shown in FIG. 1, body 12 of cartridge retainer assembly 10 includes a plurality of inwardly projecting supports 65 separated from one another by notches 62, wherein supports 65 are used to hold insert tip 20 in distal end 16 of cartridge retainer assembly 10. FIG. 2 is a cross-sectional

view of cartridge retainer assembly 10 that shows cartridge assembly 22 within a cartridge receiving chamber 68. FIGS. 1 and 2 also show an array of threads 13 on proximal end 14 of body 12 used to engage threads 41 on distal end 42 of dosing apparatus 38.

Needle mounting insert tip 20 of cartridge retainer assembly 10 includes opposed proximal and distal ends 72 and 74, respectively. As shown in FIG. 2, proximal end 72 of needle mounting insert tip 20 includes a rim 76 extending therefrom that is diametrically dimensioned to closely engage metallic sleeve 34 crimped to cartridge assembly 22 for holding rubber septum 32 in place. Distal end 74 of needle mounting insert tip 20 includes a generally annular end wall 84 having an aperture 86 extending therethrough for access by proximal point 50 of needle cannula 48. An array of outwardly disposed threads 88 is defined intermediate proximal and distal ends 72 and 74, respectively. Threads 88 are disposed and dimensioned for engaging threads on needle assembly 46.

Assembly of medication delivery pen 11 is performed by inserting cartridge assembly 22 into cartridge retainer assembly 10. More particularly, neck 30 and crimped metallic sleeve 34 of cartridge assembly 22 are inserted in a proximal to distal direction into open proximal end 14 of body 12 of cartridge retainer assembly 10. Crimped metallic sleeve 34 eventually will pass entirely through body 12, and further advancement of cartridge assembly 22 into cartridge retainer assembly 10 will require entry of crimped metallic sleeve 34 into rim 76 extending from proximal end 72 of needle mounting insert tip 20. Considerable dimensional variation and eccentricities between the neck and body of prior art cartridges are known to exist. If such eccentricities do exist, crimped metallic sleeve 34 will rest on rim 76 of insert tip 20 to center sleeve 34 relative to body 12 into a position that conforms with any dimensional inconsistencies or eccentricities in cartridge assembly 22.

Further distally directed movement of cartridge assembly 22 into cartridge retainer assembly 10 will cause shoulder 28 of cartridge assembly 22 to seat against rim 76 of insert tip 20. Rim 76 therefore defines the fully seated position of cartridge assembly 22 in cartridge retainer assembly 10 and functions to securely engage cartridge assembly 22. In this fully seated position, as shown most clearly in FIG. 2, septum 32 of cartridge assembly 22 is spaced proximally from distal wall 84 of needle mounting insert tip 20. Dosing apparatus 38 is then assembled to proximal end 14 of the body of cartridge retainer assembly 10 such that plunger rod 44 of dosing apparatus 38 engages stopper 26 of cartridge assembly 22.

Medication delivery pen 11 is used by mounting needle assembly 46 to needle mounting insert tip 20 of cartridge retainer assembly 10. This mounting is achieved by moving needle assembly 46 in a proximal direction over needle mounting insert tip 20 until the threads (not shown) of cap 56 engage external threads 88 on needle mounting insert tip 20. Threads 88 of needle mounting insert tip 20 are spaced from the extreme distal end of needle mounting insert tip 20, therefore, the initial axial advancement of cap 56 over needle mounting insert tip 20 will cause proximal point 50 of needle cannula 48 to pierce rubber septum 32 of cartridge assembly 22 prior to rotational threaded engagement of needle assembly 46 with needle mounting insert tip 20. Thus, the bevel which defines proximal point 50 will advance axially through septum 32 without a rotation that could tear rubber septum 32.

After threads of cap 56 engage threads 88 of needle mounting insert tip 20, further advancement of needle

...ly 4 ... requires relative rotation between cap 56 and ... mounting insert tip 20. It will be appreciated that needle mounting insert tip 20 is too small to be readily gripped by the user of medication delivery pen 11, and is partly covered by cap 56. However, the relative rotation can be achieved by rotating body 12 of cartridge retainer assembly 10. Since needle mounting insert tip 20 is locked to distal end 16 on body 12 of cartridge retainer assembly 10, rotation of body 12 is transmitted to needle mounting insert tip 20 and enables complete rotational engagement of needle assembly 46.

Use of medication delivery pen 11 proceeds in a conventional manner with dosing apparatus 38. Actuation of dosing apparatus 38 causes liquid medication in cartridge assembly 22 to be urged in a distal direction through lumen 51 of needle cannula 48. This distally directed liquid pressure also will cause septum 32 to distend in a distal direction. However, as noted above and as shown in FIG. 2, septum 32 is spaced proximally from cork 54 of needle assembly 46, and will not be urged into contact with cork 54. Thus, drooling or weeping of liquid medication can be substantially prevented. This is enabled because cartridge assembly 22 is supported and accurately positioned by engagement of cartridge shoulder 28 with rim 76 on insert tip 20. Hence neck 30 and crimped metallic sleeve 34 need not be closely engaged by needle mounting insert tip 20. After medication delivery pen 11 has been used, needle assembly 46 is separated from needle mounting insert tip 20 and discarded.

In the foregoing discussion, it is to be understood that the above-described embodiments of the present invention are simply illustrative of various features of a cartridge retainer assembly for a medication delivery pen. Other suitable variations, modifications and combinations of these features could be made to or used in these embodiments and still remain within the scope of the present invention.

What is claimed is:

1. A medication delivery pen for delivering medication to a patient during an injection procedure comprising:

a needle assembly having a 31 gauge needle cannula;

a cartridge assembly containing medication having a proximal and distal end, said proximal end including an array of threads and a stopper and said distal end including means for attaching said needle assembly so that medication can flow through said 31 gauge needle cannula during an injection procedure; and

a dosing apparatus having opposed proximal and distal ends with an array of threads at said distal end for threaded engagement with said threads at said proximal end of said cartridge assembly, said dosing apparatus further comprising a plunger rod projecting beyond said distal end of said dosing apparatus for selective engagement with said stopper in said cartridge assembly, and means for moving said plunger rod distally in said dosing apparatus selected amounts, whereby said plunger rod moves said stopper in said cartridge assembly to dispense medication from said cartridge assembly through said 31 gauge needle cannula.

2. A medication delivery pen according to claim 1, wherein said 31 gauge needle cannula has an outer diameter less than 0.0105 inches.

3. A medication delivery pen according to claim 1, wherein said 31 gauge needle cannula has an outer diameter no smaller than 0.010 inches and no larger than 0.0105 inches.

4. A medication delivery pen according to claim 1, wherein said 31 gauge needle cannula has an inner diameter no smaller than 0.0045 inches and no larger than 0.006 inches.

5. A medication delivery pen according to claim 1, wherein said 31 gauge needle cannula is made of stainless steel.

6. A medication delivery pen according to claim 1, wherein said 31 gauge needle cannula has a usable length of approximately 0.315 inches.

7. A medication delivery pen according to claim 1, wherein said 31 gauge needle cannula has a usable length of approximately 0.236 inches.

8. A medication delivery pen according to claim 1, wherein said 31 gauge needle cannula has a usable length of approximately 0.394 inches.

9. A medication delivery pen according to claim 1, wherein said 31 gauge needle cannula has a wall thickness no smaller than 0.00225 inches and no larger than 0.00275 inches.

* * * * *

AF/3763

Docket No. 5637.200-US

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Applicant(s) :	Buch-Rasmussen et al.		
Serial No. :	09/348,536	Examiner: Simons, K.	
Filed :	July 7, 1999	Art Unit: 3763	
Title :	Medication Delivery Device		

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Date: June 11, 2001

Box AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on June 11, 2001.

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — Signature

June 11, 2001 — Date

Transmitted herewith is an Amendment in the above-identified application.

1. ( ) No additional fee is required.

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Docket No. 5637.200-US

2. ( ) The fee has been calculated as shown below:

Claims remaining	Prior Paid Claims	Extra	Rate	Fee
Total:	minus (at least 20) =	@	$18	= $
Independent	minus (at least 3) =	@	$80	= $___
	TOTAL ADDITIONAL FEE: $			

3. (X) An extension of time to respond to the PTO Communication dated January 17, 2001 is hereby requested. The required fee is indicated below:

Within first month:	( )	$ 110
Within second month	(X)	$ 390
Within third month	( )	$ 890
Within fourth month	( )	$1,390
Within the fifth month	( )	$1,890

4. ( ) Enclosed please find a check in the amount of $ 0.00 representing (a) additional claims fee ($ 0) and (b) the extension fee ($ 0).

5. (X) The Commissioner is hereby authorized to charge the amount of $ 390.00 representing (a) additional claims fee ($); and (b) the extension fee ($ 890) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 735-3020

Docket No. 5637.200-US

D3 6-18 T15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/348,536 Examiner: Simons, K.

Filed : July 7, 1999 Art Unit: 3763

Title : Medication Delivery Device

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on June 11, 2001.

Robert B. Smith Reg. No. 28,538

Robert B. Smith June 11, 2001

Signature Date

June 11, 2001

RESPONSE AFTER FINAL REJECTION

Box AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

The applicants respectfully request reconsideration of the final rejection of claims 2-7, 10-12, and 26-28, mailed on January 17, 2001, on the grounds, discussed further below, that the Dibiasi patent fails to disclose a syringe in which one of the two claimed coupling means are provided on the **cartridge** itself, as

recited in independent claim 26. In requesting reconsideration, the applicants rely upon the Examiner's own interpretation of Dibiasi, as set forth in the final rejection.

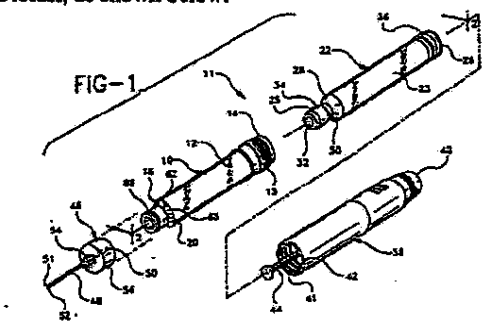
More particularly, claim 26 claims a "cartridge assembly" in combination with a "dosing assembly." The "cartridge assembly" "includes a molded cartridge" with a stopper. Claim 26 further requires that the "cartridge assembly" includes two coupling means for engaging, respectively, a needle assembly and the dosing assembly. Finally, claim 26 recites that "at least one of said coupling means is unitarily molded with the **cartridge**" (in contrast, the other coupling means can be located either on any element of the **cartridge assembly**).

In the final rejection, the Examiner rejected claim 26 as being anticipated by Dibiasi et al. U.S. patent No. 6,146,361. The Examiner applied the elements disclosed in Dibiasi to claim 26 as follows:

Claim 26	Dibiasi
a molded cartridge	cartridge 22
first coupling means to engage a needle	threads 88 on the "cartridge retainer" 10
second coupling means to engage a dosing assembly	threads 13 on the cartridge retainer 10
one of the coupling means unitarily molded with the cartridge	threads 88 and 13 are both molded on the cartridge retainer 10; thus, DiBiasi fails to disclose any coupling means on the cartridge

Final Office Action, Paragraph 2.

The European counterpart of Dibiasi is discussed in the present specification on pages 1-2. As noted therein, the "cartridge assembly" of Dibiasi includes both a cartridge and a cartridge holder. And, while the "cartridge assembly" includes two coupling means, for a needle and for the dosing housing, respectively, both coupling means are provided on the cartridge holder. Neither of the coupling means are located on the cartridge itself, as specified in claim 26. This is evident from Figure 1 of Dibiasi, as shown below:



In the final rejection, the Examiner correctly stated that the element 22 corresponds to the "cartridge" recited in claim 26. And, insofar as the Examiner found the first and second coupling means of the "cartridge assembly" recited in claim 26 could be found on the cartridge holder 10 (threads 13 and 88 of Dibiasi), it is evident that the Examiner construed the term "cartridge assembly" in claim 26 to encompass two elements of Dibiasi: the cartridge holder 10 along with the cartridge 22 itself.

Thus, insofar as claim 26 recites that the "cartridge assembly" includes a first and second coupling means, the Examiner correctly found that the

"cartridge assembly" of Dibiasi includes two coupling means. However, claim 26 does not merely specify that the cartridge assembly include the two coupling means. Claim 26 specifies that "at least one of said coupling means is unitarily molded with the cartridge."

In the final rejection, the Examiner correctly found that neither of the coupling means (threads 13 and 88) of Dibiasi were provided on the cartridge 22. Rather, the Examiner found both coupling means (threads 13 and 88) to be on the other element of the "cartridge assembly," namely, the cartridge holder 10.

Thus, Dibiasi clearly does not disclose a syringe in which "at least one of said coupling means is unitarily molded with the cartridge." For such reason, the rejection of claim 26 as anticipated by Dibiasi is unsupportable, and the applicants respectfully request the Examiner to reconsider and withdraw such rejection (as well as the rejection of the dependent claims).

Also, in connection with dependent claim 6, the Examiner states that the invention would perform equally with a glass cartridge and that the use of plastic does not serve any particular purpose. However, plastic is a preferred material because it is easy to machine and the plastic can be molded more easily with smaller tolerances. Moreover, in the case of a glass cartridge, the cartridge holder performs the function of protecting the cartridge. Where a coupling means is provided directly on the cartridge, rather than on an a cartridge holder, torque or other forces are applied directly to the glass cartridge when another component is attached to or

removed from the cartridge, which could potentially cause a glass cartridge to break. For such additional reason, the applicants respectfully request favorable reconsideration of dependent claim 6.

For all the foregoing reasons, the applicants respectfully request reconsideration and allowance of the pending claims.

Respectfully submitted,

Robert B. Smith

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PTO Registration No. 28,538
Attorney for applicant(s)
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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/348,536	07/07/99	BUCH-RASMUSSEN	T 5637.208-US

QM32/0627

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SIRMONS,K	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)
*U.S. GPO: 2000-473-000/44602

1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/348,536	Thomas Bush-Rasmussen et al
Examiner	**Art Unit**
Kevin C. Simmons	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 13, 2001*

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2-7, 10-12, and 26-28* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2-7, 10-12, and 26-28* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. Claims 26-28, 2-4, 6, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device comprising: a cartridge assembly (300&350) having opposite ends, and a dosing assembly (100), wherein said cartridge assembly includes a molded cartridge (300&350) and a stopper disposed in said cartridge (306), wherein one end (distal end of 300&350) of said cartridge assembly is sealed with a pierceable sealing (353), wherein said one end includes a first coupling means (see fig. 4) for releasably mounting a needle assembly having a skin-piercing needle (501), and wherein the other end of said cartridge assembly includes a second coupling means (303) for engaging said dosing assembly (100), wherein at least one of said coupling means is unitarily molded with the cartridge (since 300&350 in combination are the cartridge, then, 303 represents the coupling means on the distal and proximal end of the cartridge), and wherein said dosing assembly includes a housing (101),

plunger (fig. 4), and a mechanism for setting a desired dose and for moving said plunger (fig. 2&3), relative to said housing in an axial direction for administering a set dose (functional language), (figs. 2&3), and wherein said dosing assembly housing includes a coupling member (fig. 2&3) for engaging said second coupling means of said cartridge assembly (figs. 2&3); for securing said housing against axial movement relative to said cartridge assembly (figs. 2&3) and such that said plunger engages said stopper for moving said stopper in response to plunger movement (figs. 2&3); wherein both said coupling means of said cartridge assembly are unitarily molded with the cartridge (figs. 3 and 2); wherein the said at least one coupling means of said cartridge assembly is an external coupling (fig. 4); wherein the said at least one coupling means of said cartridge assembly is a threaded coupling (figs. 2&3); the coupling of the cartridge assembly are opposed (figs. 3 and 2); wherein the said at least one coupling means is said second coupling means (figs. 3 and 2); wherein said second coupling means is a threaded coupling (figs. 3 and 2); a dosing assembly with a scale (col. 5, lines 1-10); wherein the cartridge is molded of a plastic material (fig.2 and 3).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device substantially as claimed except for: wherein the cartridge is at least partly transparent (figs. 3 and 2). However, Chanoch discloses that the cartridge is made of plastic. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plastic cartridge of Chanoch since it well known that plastics can be made transparent.

Response to Arguments

5. Applicant's arguments with respect to claims 2-7, 10, 12, and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

6. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703)306-5410.

The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS

Kevin C. Sirmons

Patent Examiner

6/19/01

RICHARD K. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities – 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

06/01/01

AF/3763

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#17

Docket No. 5637.200-US

Notice of Appeal
S. Buyce
7/30/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/348,536 Examiner: Simons, K.

Filed : July 7, 1999 Art Unit: 3763

Title : Medication Delivery Device

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on June 15, 2001.

Robert B. Smith Reg. No. 28,538

Robert B. Smith
Signature

June 15, 2001
Date

June 15, 2001

NOTICE OF APPEAL

BOX AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

The applicant(s) hereby appeal(s) to the Board of Patent Appeals and Interferences from the decision dated January 17, 2001, of the Primary Examiner finally rejecting claims 2-7, 10, 12, and 26-28.

A two month extension of time has already been obtained.

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Docket No. 5637.200-US

The Commissioner is hereby authorized to charge Deposit Account No. 19-2385 the sum of $310.00 representing (a) the appeal fee ($310).

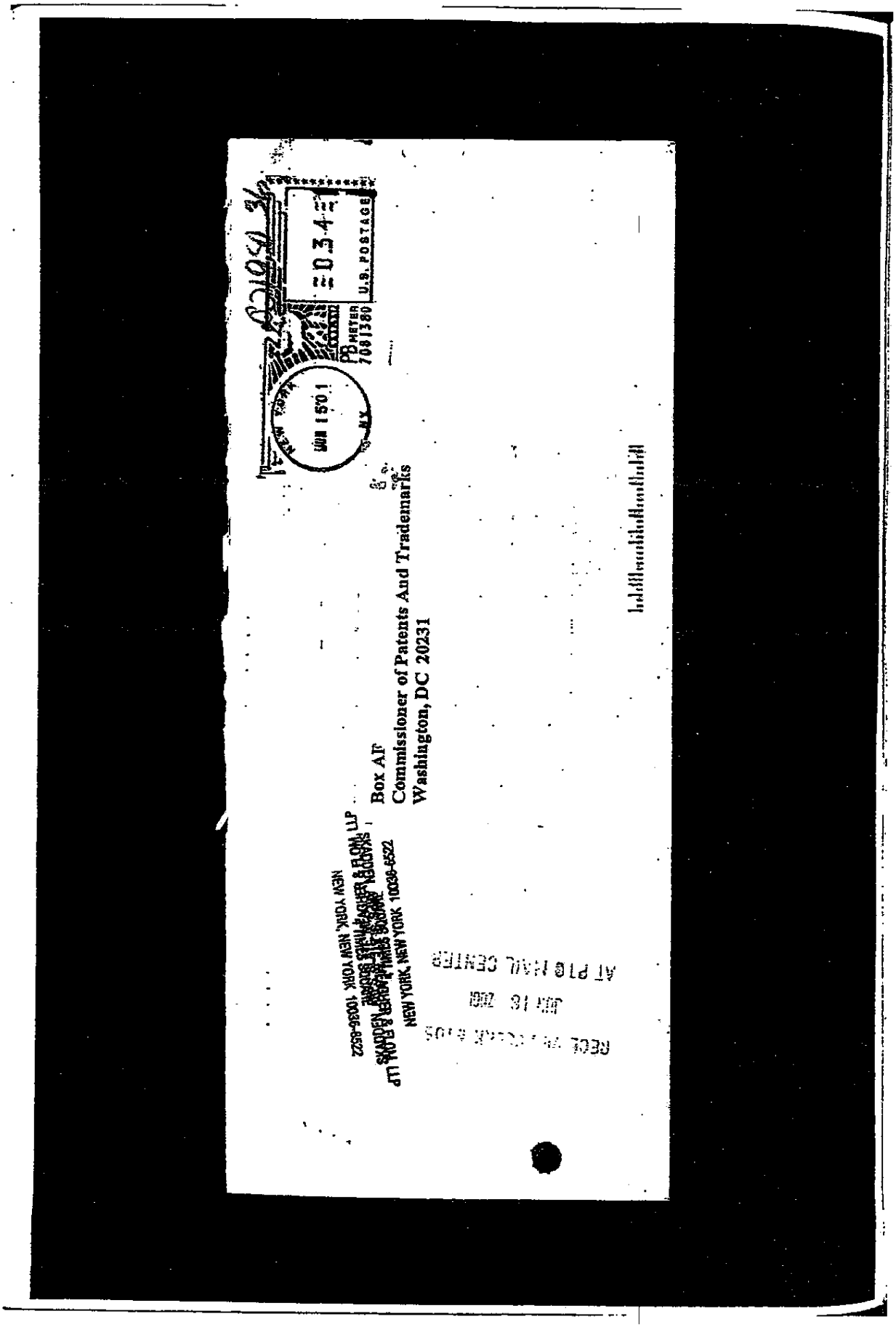
In the event that a further extension of time is needed, such extension is provisionally requested, and the Commissioner is authorized to charge payment of such extension fee, along with any additional fees required in connection with this communication, to Deposit Account No. 19-2385. A copy of this sheet is included for such purpose.

Respectfully submitted,

Robert B. Smith

Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)

Skadden, Arps, Slate, Meagher, & Flom
Four Times Square
New York, NY 10036-6522
(212) 735-3020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SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
NEW YORK, NEW YORK 10036-6522
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Docket No. 5637.200-US

#18
Rivers
1/17/02

SKADDEN, ARPS, SLATE, MEAGHER & FLOM
Four Times Square
New York, NY 10036-6522

Telephone: (212) 735-3020
Facsimile: (917) 777-3020

Date: October 25, 2001

Applicant(s)	:	Buch-Rasmussen et al.	
Serial No.	:	09/348,536	Examiner: Simons, K.
Filed	:	July 7, 1999	Art Unit: 3763
Title	:	Medication Delivery Device	

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2001.

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — October 25, 2001
Signature — Date

Transmitted herewith is an AMENDMENT in the above-identified application.

1. ( ) No additional fee is required.

Docket No. 5637.200-US

2. ( ) The fee has been calculated as shown below:

Claims remaining	Prior Paid Claims	Extra	Rate	Fee
Total:	minus (at least 20) =	@	$18 =	$
Independent	minus (at least 3) =	@	$80 =	$___
	TOTAL ADDITIONAL FEE: $			

3. (X) An extension of time to respond to the PTO Communication dated June 27, 2001 is hereby requested. The required fee is indicated below:

Within first month:	(X)	$110
Within second month	( )	$390
Within third month	( )	$890
Within fourth month	( )	$1,390

4. ( ) The Amendment includes an Information Disclosure Statement. Enclosed is Form PTO-1449 and copies of ____ reference(s).

5. (X) The Commissioner is hereby authorized to charge the amount of $ 110.00 representing (a) additional claims fee ($); (b) the extension fee ($ 110); and (c) the fee for filing an Information Disclosure Statement ($) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 735-3020

COPY

Docket No. 5637.200-US

SKADDEN, ARPS, SLATE, MEAGHER & FLOM
Four Times Square
New York, NY 10036-6522

Telephone: (212) 735-3020
Facsimile: (917) 777-3020

Date: October 25, 2001

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/348,536 Examiner: Simons, K.

Filed : July 7, 1999 Art Unit: 3763

Title : Medication Delivery Device

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2001.

Robert B. Smith Reg. No. 28,538

Robert B Smith
Signature

October 25, 2001
Date

Transmitted herewith is an AMENDMENT in the above-identified application.

1. ( ) No additional fee is required.

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01 FC:115 110.00 CH

Docket No. 5637.200-[

2. ( ) The fee has been calculated as shown below:

Claims remaining	Prior Paid Claims	Extra	Rate	Fee
Total:	minus (at least 20) =		@ $18	= $
Independent	minus (at least 3) =		@ $80	= $

TOTAL ADDITIONAL FEE: $

3. (X) An extension of time to respond to the PTO Communication dated June 27, 2001 is hereby requested. The required fee is indicated below:

Within first month:	(X)	$110
Within second month	( )	$390
Within third month	( )	$890
Within fourth month	( )	$1,390

4. ( ) The Amendment includes an Information Disclosure Statement. Enclosed is Form PTO-1449 and copies of ____ reference(s).

5. (X) The Commissioner is hereby authorized to charge the amount of $ 110.00 representing (a) additional claims fee ($); (b) the extension fee ($ 110); and (c) the fee for filing an Information Disclosure Statement ($) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 735-3020

Docket No. 5637.200-US

#19 ARGUED 1/17/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/348,536 Examiner: Simons, K.

Filed : July 7, 1999 Art Unit: 3763

Title : Medication Delivery Device

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2001.

Robert B. Smith Reg. No. 28,538

Robert B. Smith
Signature

October 25, 2001
Date

October 25, 2001

RESPONSE TO OFFICE ACTION

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

The applicants respectfully request reconsideration of the rejection of claims 2-7, 10-12, and 26-28, mailed on June 27, 2001. The applicants respectfully request, in particular, that the Examiner reconsider the assertion that the cartridge holder element 300 of the cited Chanoch patent can be deemed to be part of a

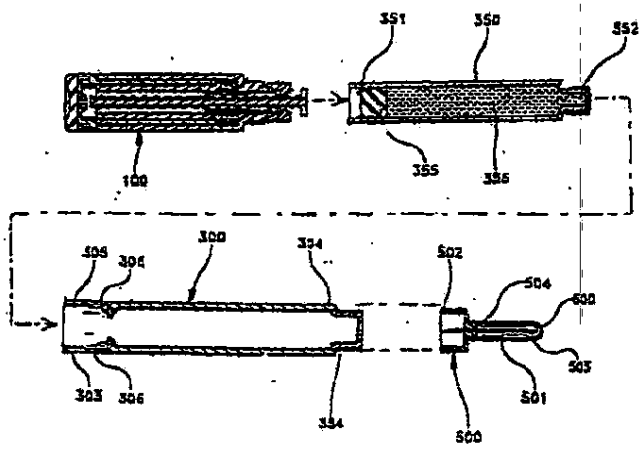
"molded cartridge" element as recited in claim 26. In requesting reconsideration, the applicants note that the Examiner's position that the cartridge holder 300 of Chanoch can be deemed to be part of a "molded cartridge" as recited in claim 26 is inconsistent with the Examiner's interpretation of DiBiasi U.S. patent No. 6,146,361, set forth in the final rejection dated January 17, 2001. In previously applying DiBiasi to claim 26, the Examiner asserted that the element in DiBiasi corresponding to the "molded cartridge" in claim 26 constitutes the cartridge 22 only, and not the cartridge holder.

Claim 26 claims a "cartridge assembly" that includes a "molded cartridge" with a stopper. Claim 26 further requires that the "cartridge assembly" includes two coupling means for engaging, respectively, a needle assembly and the dosing assembly. Finally, claim 26 recites that "at least one of said coupling means is unitarily molded with the cartridge" (i.e., at least one of the coupling means must be unitarily molded with the cartridge, and not merely associated with the cartridge assembly).

Chanoch U.S. patent No. 5,688,251 discloses a pen type syringe which includes a "cartridge holder assembly 300" that includes "a molded housing 304." Col. 5, lines 50-51. A "medication cartridge 350 [is] securely retained in housing 304." Col. 6, lines 1-2. More particularly, a "cap 354 extends between housing 304 and cartridge 350 for securely and permanently holding medication cartridge in housing 304." Col. 6, lines 3-8. Finally, a needle cannula assembly 500

has a mounting hub 504 which is "threadingly engageable with the cap 354." Col. 6, lines 15-20.

The disclosure that, but for the cap 354, the cartridge 350 can be separated from the cartridge holder housing 304 means that the housing 304 and cartridge 305 are separate elements, which are mechanically coupled to one another during some stage of the assembly process. Thus, if Fig. 2 of Chanoch were modified to show the parts of the syringe prior to such assembly, it would be as follows:



Thus, as evident from the Chanoch specification, the cartridge holder 300 is not molded unitarily with the cartridge 350 - they are separate elements.

As discussed above, claim 26 recites two coupling means for engaging, respectively, a needle assembly and the dosing assembly, and recites that "at

least one of said coupling means is unitarily molded with the [molded] cartridge." Chanoch discloses two coupling means: (1) internal threads 303 formed in the barrel of the cartridge holder 300 (which engage cooperating threads on the pen body 100), Col. 5, lines 55-57; and (2) threads on the external surface of the cap 354 (which engage internal threads provided in the needle hub 504). Col. 6, lines 18-20. Thus, Chanoch disclose two coupling means for engaging, respectively, a needle assembly and a dosing assembly. However, in Chanoch both such coupling means are provided on the cartridge holder, not on the "molded cartridge" itself. Thus, Chanoch does not anticipate or suggest claim 26.

The commonly owned Chanoch and DiBiasi patents both show a syringe having a cartridge holder element which screws onto a pen body. Both the cartridge holder of Chanoch and the cartridge holder of DiBiasi receive a separate cartridge. The difference between Chanoch and DiBiasi is that, in Chanoch, once the cartridge is inserted in the cartridge holder barrel, it cannot be removed. Thus, when the cartridge is empty, the user must replace both the cartridge and the cartridge holder. In contrast, DiBiasi allows the cartridge to be removed from the cartridge holder when empty, so that only the cartridge, and not the cartridge holder needs to be replaced. This difference is immaterial relative to the claims of the present application.

As discussed in the applicants's Response After Final Rejection dated June 11, 2001, in applying DiBiasi to claim 26, the Examiner did not consider the

cartridge holder to be part of the claimed "molded cartridge." Rather, the Examiner deemed the cartridge 22 of DiBiasi to correspond to the "molded cartridge" of claim 26, and treated the "cartridge retainer" 10 of DiBiasi to constitute a separate element. Final Office Action, Paragraph 2.

The cartridge holder and cartridge shown in DiBiasi are very similar to the cartridge holder and cartridge shown in Chanoch, except that, in Chanoch, the cartridge is permanently retained in the cartridge holder (and insofar as the cartridge holder barrel in Chanoch has internal threads to engage the pen body). Thus, it is inconsistent for the Examiner to deem the cartridge (but not the cartridge holder) to constitute a "molded cartridge" when interpreting DiBiasi, and yet to deem both the cartridge and the cartridge holder to constitute a "molded cartridge" when interpreting Chanoch.

For such reason, the applicants do not believe that the combination of the cartridge 350 and the cartridge holder 300 of Chanoch can properly be deemed to correspond to a "molded cartridge." Certainly, a person skilled in the art would not deem a cartridge holder to be part of a molded cartridge, as evidenced by the fact that the Chanoch specification clearly differentiates between a cartridge and a cartridge holder. *See, Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1578, 38 U.S.P.Q.2d 1126, 1129 (Fed. Cir. 1996) (stating that a claim term is to be given the meaning that it would be given by persons experienced in the field of invention).

Because the rejection of the claims hinges on the assertion that the cartridge holder 300 of Chanoch is part of a "molded cartridge," the applicants respectfully request reconsideration and allowance of the pending claims.

Respectfully submitted,

Robert B. Smith
PTO Registration No. 28,538
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